



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0905; FRL-10798-02-OCSPP]

1,4-Dioxane; Draft Supplement to the TSCA Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Meeting and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or “Agency”) is announcing the availability of and soliciting public comment on the “2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation” prepared under the Toxic Substances Control Act (TSCA) that is being submitted to the Science Advisory Committee on Chemicals (SACC) for peer review. The draft supplement is available for public review and comment and is submitted to the SACC for peer review. The SACC will consider and review the draft supplement at a 4-day virtual public meeting that was previously announced in the *Federal Register* of March 23, 2023. The virtual public meeting will be held on September 12-15, 2023, via a webcast platform such as “Zoomgov.com” and audio teleconference.

DATES: The following is a chronological listing of the dates for the specific activities that are described in more detail under **SUPPLEMENTARY INFORMATION**.

September 1, 2023 – Deadline for submitting a request for special accommodations to allow EPA time to process the request before the meeting.

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] – Deadline for providing written comments on the draft supplement.

September 8, 2023 – Deadline for registering to be listed on the meeting agenda to make oral comments during the virtual meeting.

September 15, 2023 – Deadline for those not making oral comments to register to receive the links to observe the meeting.

ADDRESSES: *To comment:* Submit written comments, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0905, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Copyrighted material will not be posted without explicit permission from the copyright holder. Members of the public should also be aware that personal information included in any written comments may be posted on the internet at <https://www.regulations.gov>. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

To register for the meeting: For information on how to register and access the virtual public meeting, please refer to the SACC website at <https://www.epa.gov/tsca-peer-review>. EPA intends to announce registration instructions on the SACC website by mid-August of 2023. You may also subscribe to the following listserv for alerts regarding this and other SACC-related activities at https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101.

To request special accommodations: For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: The DFO, Dr. Alaa Kamel, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-5336 or SACC main office number: (202) 564-8450; email address: kamel.alaa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What action is the Agency taking?

EPA is announcing the availability of and soliciting public comment on the “2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation.” EPA is also announcing a 4-day virtual public meeting on September 12-15, 2023, for the SACC to consider and review the draft supplement. This September 2023 meeting was previously announced in the *Federal Register* of March 23, 2023 (88 FR 17566 (FRL-10798-01-OCSPP)). EPA will be soliciting comments from the SACC on the methodologies utilized in the 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation that have not been previously peer reviewed. EPA is also releasing for public comment an updated risk determination for 1,4-dioxane (see docket ID No. EPA-HQ-OPPT-2016-0723). EPA is not soliciting comments from the SACC on the risk determination for 1,4-dioxane.

This document provides instructions for accessing the materials provided to the SACC, submitting written comments, and registering to provide oral comments and attend the virtual meeting.

B. What is the Agency's authority for taking this action?

The SACC was established by EPA in 2016 in accordance with the Toxic Substances Control Act (TSCA), 15 U.S.C. 2625(o), to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. The SACC operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. 10, and supports activities under the TSCA, 15 U.S.C. 2601 *et seq.*, the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.*, and other applicable statutes.

C. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, and disposal of chemical substances and mixtures, and/or those interested in the assessment of risks involving chemical substances

and mixtures regulated under TSCA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

D. What should I consider as I submit my comments to EPA?

1. Submitting CBI.

Contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** for instructions before submitted CBI or other sensitive information. Do not submit this information to EPA electronically (e.g., through <https://www.regulations.gov> or email). Clearly mark the part or all of the information that you claim to be CBI. For confidential information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments.

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>. See also the instructions in Unit III.C.

II. Background

A. What is the purpose of the SACC?

The SACC provides independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. The SACC is comprised of experts in toxicology; environmental risk assessment; exposure assessment; and related sciences (e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic modeling (PBPK), computational toxicology, epidemiology, environmental fate, and environmental engineering and

sustainability). The SACC currently consists of 19 members. When needed, the committee will be assisted by *ad hoc* reviewers with specific expertise in the topics under consideration.

B. Why did EPA develop these documents?

TSCA requires EPA to conduct risk evaluations on prioritized chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations. The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk to human health or the environment under the conditions of use. These evaluations include assessing unreasonable risks to relevant potentially exposed or susceptible subpopulations. As part of this process, EPA: (1) integrates hazard and exposure assessments using the best available science that is reasonably available to assure decisions are based on the weight of the scientific evidence; and (2) conducts peer review for risk evaluation approaches that have not been previously peer reviewed.

1,4-Dioxane was one of the first 10 chemical substances undergoing the TSCA risk evaluation process after passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA in 2016. 1,4-Dioxane is primarily used as a solvent in a variety of commercial and industrial applications such as the manufacture of other chemicals (*e.g.*, adhesives, sealants) or as a processing aid or laboratory chemical. Although there are no direct consumer uses of 1,4-dioxane, it is present as a byproduct in commercial and consumer products from several manufacturing processes, including ethoxylation, sulfonation, sulfation, and esterification.

In the 2019 Draft Risk Evaluation for 1,4-Dioxane (see <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0011>), EPA reviewed the exposures and hazards of 1,4-dioxane direct industrial and commercial uses assessing risk from occupational exposures and surface water exposures to environmental organisms. This assessment, which included the physical and chemical properties, lifecycle information, environmental fate and transport information, and hazard identification and dose-response

analysis was reviewed by the SACC. The Agency considered the SACC feedback and is not seeking additional review at this time as this information has not changed.

In November of 2020, EPA released for public comment a Draft Supplement to the 2019 Draft Risk Evaluation (see <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0067>). The November 2020 Draft Supplement assessed eight conditions of use (COUs) of 1,4-dioxane as a byproduct in consumer products and general population exposure from incidental contact with surface water. The Agency determined that the additional analysis did not warrant SACC review.

The 2019 Draft Risk Evaluation and 2020 Draft Supplement were both incorporated into the final Risk Evaluation for 1,4-Dioxane released in December 2020 (see https://www.epa.gov/sites/default/files/2020-12/documents/1._risk_evaluation_for_14-dioxane_casrn_123-91-1.pdf). After its release, EPA determined an additional supplement to the final Risk Evaluation for 1,4-Dioxane was needed to consider critical exposure pathways not previously assessed. Specifically, the 2023 Draft Supplement includes evaluation of additional conditions of use in which 1,4-dioxane is present as a byproduct in industrial processes and commercial products and evaluates risks from general population exposures to 1,4-dioxane released to ambient surface water and groundwater, ambient air, and land. To evaluate these additional exposure pathways, the Agency used new methods and novel applications of existing methods. These new methods described below have not been the subject of public comment or peer review for applications in TSCA risk evaluations.

In this 2023 Draft Supplement, EPA is relying on the physical and chemical properties, lifecycle information, environmental fate and transport information, and hazard identification and dose-response analysis presented in the December 2020 final Risk Evaluation for 1,4-Dioxane, thus, EPA is not seeking feedback on these topics. However, EPA is seeking review of the methodologies listed below that have not been previously peer reviewed and are utilized in this 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation.

1. EPA applied Monte Carlo modeling in the assessment of 1,4-dioxane occupational exposures and environmental releases.

The Agency has utilized Monte Carlo approaches in TSCA risk evaluations previously for specific conditions of use; however, the application of Monte Carlo methods in the “2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation” was expanded to capture additional exposure and release models for additional conditions of use. The expanded application of these methods incorporates randomness and variability to improve the representativeness of the resulting model outputs. This was done to further improve exposure and release estimates and is in response to previous SACC review comments received on the first 10 chemical risk evaluations conducted under amended TSCA.

2. EPA assessed hydraulic fracturing as a condition of use.

This evaluation required consideration of new field operations data that have not yet been considered in TSCA risk evaluations to estimate occupational exposures and environmental releases from these operations. EPA has developed a new generic exposure scenario for hydraulic fracturing and applied it in the 2023 Draft Supplement along with the Monte Carlo modeling to estimate a range of potential releases.

3. EPA assessed the ambient air pathway to determine exposures and associated risks to fenceline communities (a subset of the general population).

The Agency assessed general population exposures via the inhalation route through both single- and multi-year analyses. The single-year analysis utilized the Fenceline 1.0 methodology described in the “EPA Toxic Substances Control Act (TSCA) Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities,” previously peer reviewed by the SACC (see, EPA (2022). Peer Review of the EPA TSCA Screening Level approach for Assessing Ambient Air and Water Exposures to Fenceline Communities March 15-17, 2022. <https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0415/document>.) EPA quantitatively characterized exposures and risks to communities in proximity to multiple

facilities releasing 1,4-dioxane to air.

4. EPA assessed general population exposures via drinking water sourced from groundwater and surface water.

Although the 2020 1,4-dioxane risk evaluation considered incidental oral and dermal exposures to surface water, the 2020 analysis did not consider drinking water exposures through sourcing of 1,4-dioxane contained in surface water or groundwater.

a. Surface water.

- 1,4-Dioxane concentrations in surface water reported in the 2023 draft supplemental risk evaluation were modeled based on known facility and publicly owned treatment works releases directly to surface water. This methodology is generally consistent with what was previously done to aquatic exposures and presented in the draft Fenceline 1.0 methodology previously reviewed by the SACC. However, this analysis was modified to include consideration of multiple years of release data, as recommended by SACC, and integrated NHDPlus flow networks and flows to modernize approaches previously utilized in TSCA risk evaluations. This assessment is the first time the modified approach has been employed in a TSCA risk evaluation.

- 1,4-Dioxane concentrations resulting from consumer and commercial down-the-drain releases of 1,4-dioxane through publicly owned treatment works to surface water were estimated. EPA used the Stochastic Human Exposure and Dose Simulation Model (SHEDS) for high-throughput (HT) (SHEDS-HT) model (see Environ. Sci. Technol. 2014, 48, 21, 12750–12759) predictions to estimate down-the-drain disposals (Isaacs, 2014). SHEDS-HT was developed by EPA under the ExpoCast program for evaluating chemicals based on the potential for biologically relevant human exposure. This is the first TSCA risk evaluation incorporating down-the-drain estimates based on SHEDS-HT model predictions and is the first time the down-the-drain model has been used for one of the first 10 chemical risk evaluations conducted under amended TSCA.

- 1,4-Dioxane concentrations in surface water were modeled based on multiple upstream

sources, including releases from facilities and publicly owned treatment works and down-the-drain releases. In addition, EPA compared the modeled concentrations to drinking water monitoring data for community water systems. This approach to considering the contribution of multiple sources to drinking water exposures is novel. EPA has not previously considered multiple sources of releases when estimating exposure concentrations in surface water for a chemical risk evaluation under TSCA.

b. Groundwater.

- 1,4-Dioxane concentrations in groundwater were modeled for two disposal pathways by applying the Delisting Risk Assessment Software (DRAS) model in a novel way. DRAS is a multi-pathways model developed by the EPA that calculates the potential human health risks associated with disposing of a specific facility's given waste stream in a landfill or surface impoundment. (See U.S. EPA. (2020). Hazardous Waste Delisting Risk Assessment Software Version 4. Lenexa, KS: EPA Region 6. <https://www.epa.gov/hw/hazardous-waste-delisting-risk-assessment-software-dras>.) DRAS was specifically designed to address the Criteria for Listing Hazardous Waste. The 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation presents a novel application of this model and the first application in a TSCA chemical risk evaluation. Specifically, EPA compared the modeled concentrations to monitoring data from groundwater contaminations around the nation to consider if they are within a reasonable range.

EPA is also seeking review of the overall synthesis of the results of these novel methodologies and the integration of the results into the 1,4-Dioxane Risk Evaluation. Feedback from this review will be considered in the development of the final supplement to the 1,4-dioxane risk evaluation. In addition, SACC reviewer feedback may help refine EPA's methods for conducting release assessments and evaluating general population exposures in risk evaluations of other chemicals under TSCA.

III. Virtual public Meeting of the SACC

A. What is the purpose of this public meeting?

The purpose of the 4-day virtual public meeting is the SACC peer review of the methodologies that have not been previously peer reviewed and are utilized in the 2023 Draft Supplement. Feedback from this review will be considered in the development of the final Supplement to the Risk Evaluation for 1,4-Dioxane. In addition, SACC reviewer feedback may help refine EPA's methods for conducting release assessments and evaluating general population exposures in risk evaluations of other chemicals under TSCA.

EPA intends to provide a meeting agenda for each day of the meeting, and as needed, may provide updated times for each day in the meeting agenda that will be posted in the docket and on the SACC website.

B. How can I access the documents submitted for review to the SACC?

The 2023 Draft Supplement and related documents, including background documents, related supporting materials, and draft charge questions provided to the SACC, are available in the docket. As additional background materials become available and are provided to the SACC, EPA will include those additional background documents (*e.g.*, SACC members and consultants participating in this meeting and the meeting agenda) in the docket. All of these documents will be available through <https://www.regulations.gov> (docket ID No. EPA-HQ-OPPT-2022-0905) and through links on the SACC website at <https://www.epa.gov/tsc-peer-review>.

After the public meeting, the SACC will prepare meeting minutes and a final report document summarizing its recommendations to the EPA. This document will also be available in the docket and the SACC website.

C. How can I provide comments for the SACC's consideration?

To ensure proper receipt of comments it is imperative that you identify docket ID No. EPA-HQ-OPPT-2022-0905 in the subject line on the first page of your comments and follow the instructions in Unit I.D. and in this unit.

1. Written comments.

The Agency encourages written comments for this meeting be submitted by the deadlines

set in the **DATES** section of this document and following the instructions in this document.

2. Oral comments.

The Agency encourages each individual or group wishing to make brief oral comments to the SACC during the peer review virtual public meeting to follow the registration instructions that will be announced on the SACC website by mid-August of 2023. Oral comments before the SACC during the peer review virtual public meeting are limited to 5 minutes. In addition, each speaker should submit a written copy of their oral comments and any supporting materials (e.g., presentation slides) to the DFO prior to the meeting for distribution to the SACC by the DFO.

D. How can I participate in the virtual public meeting?

The virtual public meeting will be held via a webcast platform such as “Zoomgov.com” and audio teleconference. You must register online to receive the webcast meeting link and audio teleconference information. Please follow the registration instructions that will be announced on the SACC website.

Authority: 15 U.S.C. 2625(o); 5 U.S.C 10.

Dated: July 3, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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